

**Please provide information about your company:**

**Name of Contact Person:** \_\_\_\_\_

**Title of Contact Person:** \_\_\_\_\_

**Manufacturer:** \_\_\_\_\_

**Street Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Country:** \_\_\_\_\_

**Postal Code:** \_\_\_\_\_ **Email Address:** \_\_\_\_\_

**Telephone:** \_\_\_\_\_ **FAX:** \_\_\_\_\_

**Please provide information about your device:**

**Planned date of submission:** \_\_\_\_\_

**Purpose of submission:**  **New Device**  **Additional Indications**

**Change in technology, materials, design, or manufacturing process**

**Other:** \_\_\_\_\_

**Product Code:** \_\_\_\_\_ **CFR Section:** \_\_\_\_\_

**Classification Panel:** \_\_\_\_\_

**Device Classification:**  **Class I**  **Class II**

**Common Name:** \_\_\_\_\_

**Trade or Proprietary Name:** \_\_\_\_\_

**Name of Legally Marketed Comparison Device:** \_\_\_\_\_

**510(k) Control Number:** \_\_\_\_\_

**Date Cleared:** \_\_\_\_\_